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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,583	LANGSTON, PHIL	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a catheter.

II. Claims 13-14, drawn to a method of measuring differential pressure.

III. Claims 15-22, drawn to a method of manufacturing a catheter.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case invention I may be used for a different process, such as for delivering a drug to a patient.

3. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case invention I may be formed by putting a first single lumen portion through a larger single lumen to

form a double lumen portion, rather than by connecting a single lumen to a double lumen, as specified in invention III.

4. Inventions II and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions are not obvious variants, as the method of invention II may be performed by a device substantially different than one formed by the method of invention III.

5. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Paul Onderick on 5 May 2006 a provisional election was made with traverse to prosecute invention I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 1, 2, 6, 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin'380 (US Patent 5480380) in view of Ladika'840 (US Patent 4747840).

Regarding Claim 1, Martin'380 discloses a catheter comprising a manifold portion (element 24) comprising a first connector and a second connector (elements 36 and 38) (see Figure 1); a coaxial dual lumen portion (element 22) comprising an inner lumen wall in communication with one connector and an outer lumen wall in communication with the other connector (see Figure 8), where the distal end of the outer lumen wall contains a plurality of perforations (elements 48); and a single lumen portion with a generally straight portion (Figure

1) in fluid communication with the inner lumen portion (see Figure 6), where the lumen wall contains at least one side hole (element 50). Martin'380 does not disclose the single lumen portion comprising a pigtail portion distal to a straight portion of the single lumen.

Ladika'840 teaches a catheter comprising a single lumen portion with a straight section (element 26) and a pigtail portion (element 18) distal to the straight portion (see Figure 1), in order to prevent the catheter from puncturing the patient's tissues (column 1, lines 60-66).

It would have been obvious to one of ordinary skill in the art to have formed the catheter of Martin'380 and added the distal pigtail section of Ladika'840, in order to prevent the catheter from puncturing the patient's tissue.

Regarding Claim 2, Martin'380 further discloses the presence of a tapering portion (element 66) between the dual and single lumen sections of the device (see Figure 6).

Regarding Claim 6, Martin'380 discloses all the elements of the current invention, as applied to Claim 1 above, except for the inner lumen side holes being distributed in a spiral pattern over about 2 centimeters.

Ladika'840 further teaches that the single lumen portion comprises side holes that are distributed in a spiral array, in order to evenly distribute fluids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840, and distributed the inner lumen side holes in a spiral array, as taught by Ladkika'840, in order to evenly distribute fluids.

Regarding Claim 8, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 1 above, except for the single lumen portion further comprising a second straight portion joined to the first straight portion by a bend.

Ladika'840 further teaches that the single lumen portion of the catheter comprises a second straight portion (element 28) joined to the first straight portion (element 26) by a bend (element 22) (see Figure 1), in order to allow easier maneuvering inside a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840, and added the second straight portion to the single lumen section, as taught by Ladika'840, in order to allow easier maneuvering inside a patient.

Regarding Claim 9, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 8 above, except for the angle between the first and second straight portions of the inner lumen being between about 130 and about 160 degrees.

Ladika'840 further teaches that the bend (element 22) between straight portions (elements 28 and 30) is between about 130 and about 160 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'480 in view of Ladika'840, and formed the bend between straight portions of the inner lumen to

be between about 130 and about 160 degrees, as taught by Ladika'840, in order to properly maneuver within a patient's heart.

Regarding Claim 10, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 9 above, except for the angle of the bend being about 145 degrees.

Ladika'840 further teaches that the angle of the bend is about 145 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'480 in view of Ladika'840, and formed the bend between straight portions of the inner lumen to be about 145 degrees, as taught by Ladika'840, in order to properly maneuver within a patient's heart.

Regarding Claims 11 and 12, MPEP section 2113 states:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin'380 in view of Ladika'840. Since the end result product meets the recited structure, the manner of making is not limiting.

10. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin'380 in view of Ladika'840 as applied to claims 1, 2, 6, 8, 9-12 above, and further in view of Miller'640 (US Patent 5683640).

Regarding Claim 3, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 1 above, except for the dual lumen portion having a diameter of greater than 6 French and the single lumen portion having a diameter less than or equal to 6 French.

Miller'640 discloses a dual-lumen catheter comprising a dual lumen portion with a diameter of greater than 6 French and a single lumen portion with a diameter of less than or equal to 6 French (column 4, lines 3-8), so that the device will properly fit within the vessels of a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840 with the dimensions of Miller'640, so that the device will properly fit within the vessels of a patient.

Regarding Claim 4, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 3 above, except for the dual lumen portion having a diameter of between about seven French and about 8 French.

Miller'640 further discloses that the dual lumen portion of the catheter has a diameter between about 7 and about 8 French (column 4, lines 3-5), so that the device properly fits within a patient's vessels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840 with the dual lumen portion dimensions of Miller'640, so that the device properly fits within a patient's vessels.

Regarding Claim 5, Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 3 above, except for the single lumen portion having a diameter of about 5 French.

Miller'640 further discloses that the single-lumen portion of the catheter has a diameter of about 5 French (column 4, lines 6-7), so that it may easily maneuver within a patient's vessels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840 with the single lumen portion dimensions of Miller'640, so that the device may easily maneuver within a patient's vessels.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin'380 in view of Ladika'840 as applied to claims 1, 2, 6, 8, 9-12 above, and further in view of Duffy'332 (US Patent 6048332).

Martin'380 in view of Ladika'840 discloses all the elements of the current invention, as applied to Claim 1 above, except for the outer lumen side holes being distributed spirally over about 4 centimeters of the lumen.

Duffy'332 teaches a catheter comprising an outer lumen (element 20) with spirally distributed holes (element 32) (see Figures 4 and 5b), wherein the length

of the portion with the holes is about 4 centimeters (column 8, lines 42-45), in order to properly interact with the patient's fluids.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin'380 in view of Ladika'840 with the spirally distributed holes of Duffy'322, in order for the device to properly interact with the patient's fluids.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5346471 to Raulerson, which discloses a dual lumen catheter.
US Patent 5976103 to Martin, which discloses a dual lumen coaxial catheter.
US Patent 5961485 to Martin, which discloses a dual lumen coaxial catheter.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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